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PROVISIONAL APPLICATION COVER SHEET

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| | INVENTOR(s)/APPLICANT(s) | | | | | | | | |
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| \perp | TITLE OF THE INVENTION (280 characters max) | | | | | | | | |
| | METHOD FOR INCREASING PET ACTIVITY | | | | | | | | |
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| F F | ENCLOSED APPLICATION PARTS (check all that apply) | | | | | | | | |
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| .Ŭ ≅ | A check or money order is enclosed to cover the Provisional filing fees The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: 08-2290 PROVISIONAL FILING FEE AMOUNT (5) | | | | | | | | |
| This invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. No. Yes, the name of the U.S. Government agency and the Government contract number are | | | | | | | | | |
| | spectfully submitted, | Q£ | > | Date 9 | 120/19 | | | | |
| Τ¥ | TYPED or PRINTED NAME Robert M. Barrett REGISTRATION NO. (if appropriate) 30, Additional inventors are being named on senarately numbered sheets attached here to | | | | | | | | |

PROVISIONAL APPLICATION FILING ONLY

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

Czarnecki et al.

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INVENTION:

"METHOD FOR INCREASING PET ACTIVITY"

Assistant Commissioner for Patents

Washington, D.C. 20231

CERTIFICATE OF MAILING BY EXPRESS MAIL

Sir:

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I hereby certify that the following documents relating to the above-identified application

were deposited in the United States Postal Service Express Mail "Post Office to Addressee" on

September 22, 1999:

1. Provisional Application Cover Sheet (in duplicate);

2. Specification (11 Pages);

3. Check in the amount of \$150.00; and

4. Return Receipt Postcard.

Signature of person mailing Express Mail

September 22, 1999

Express Mail Label No. EL 345 371 146 US

Patent Application

Title: Method for increasing pet activity

| Increasing pet activity
| Inventors: G. Czarnecki
| Increasing pet activity
| Inventors: E. Schiffrin

Field of the invention

This invention relates to a method of increasing the activity of pet; especially elderly cats and dogs.

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Background of the invention

Oncepets reach an age where their systems start to slow down, certain symptoms of aging begin to manifest themselves; joint stiffness, energy loss, weight gain, increased water intake, digestive system problems, a dull, dry coat and flaky skin. For dogs, this usually starts becoming noticeable at about 5 years for larger breeds and about 7 years for smaller breeds. For cats, this usually starts becoming noticeable at about 7 years. However, the process is different for every animal and there is no standard

age at which the symptoms become manifest.

The onset of many of these symptoms may be delayed by feeding the animal a complete, well-balanced diet over its life. Further, the condition of the elderly animal can be improved through nutrition. In particular, healthy animals should be fed a balanced, maintenance food that contains high quality protein, lower amounts of fat to reduce energy intake, dietary fiber, and antioxidants. Also, regular exercise is important to maintain muscle tone, enhance circulation, promote digestion and prevent weight gain.

However, despite good nutrition and regular exercise, many older animals are lethargic and appear to lack energy. Similar problems may also occur in younger animals.

Therefore there remains a need for ways of improving the activity of pets; especially older pets.

Summary of the invention

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Accordingly, in one aspect, this invention provides a method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastrointestinal tract of the pet.

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It has been surprisingly discovered that administering to a pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro 5

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intestinal tract of the pet results in improved activity levels in the pet. This is particularly noticeable in elderly pets. Without wishing to be bound by theory, it is believed that, amongst other mechanisms, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet produces nutrients and/or increases the absorption of nutrients which provides the pet with better nutrition and more energy. Further, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet reduces the concentrations of pathogenic bacteria in the gastro-intestinal tract and this may improve systemic inflammatory status; leading to less joint stiffness.

In another aspect, this invention provides a method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

The pet is preferably an elderly pet; especially an elderly dog. The dog may be older than 5 years of age; for example older than 7 years of age. The cat may be older than 7 years of age.

Preferably the nutritional agent is administered to the pet in the form of a complete and nutritionally balanced pet food.

The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from the fermentation of probiotic micro-organisms.

In this specification:-

"Prebiotic" means a substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth or development of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet at the expense of pathogenic bacteria. The result of this fermentation is a release of fatty acids, in particular short-chain fatty acids in the colon. This has the effect of reducing the pH value in the colon.

"Probiotic micro-organism" means a micro-organism which beneficially affects a host by improving its intestinal microbial balance (Fuller, R; 1989; L. Applied Bacteriology, 66: 365-378). In general, probiotic micro-organisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as Clostridium perfringens and Helicobacter pylori.

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Detailed description of the presently preferred embodiments of the invention.

This invention is based upon the discovery that the activity levels in a pet may be improved by administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The activity levels of elderly pets, such as elderly dogs, is particularly improved.

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The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from fermentation of a probiotic micro-organism. Further, combinations of the prebiotics, probiotic micro-organisms and fermentation products may be administered to the pet.

Suitable prebiotics include oligosaccharides, such as inulin and its hydrolysis products commonly known as fructooligosaccharides, galactooligosaccarides, xylo-oligosaccharides or oligo derivatives of starch. Combinations of starches and gums may also be used.

The prebiotics may be provided in any suitable form. For example, the prebiotic may be provided in the form of plant material which contains the prebiotic. Suitable plant materials includes asparagus, artichokes, onions, wheat, yacon or chicory, or residues of these plant materials. Alternatively, the prebiotic may be provided as an inulin extract. Extracts from chicory are particularly suitable. Suitable inulin extracts may be obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftiline". For example, the inulin may be provided in the form of Raftiline®ST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 9% by weight of sucrose. Alternatively, the prebiotic may be in the form of a fructooligosaccharide such as obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftilose". For example, the inulin may be provided in the form of Raftilose®P95. Otherwise, the fructooligosaccharides may be obtained by hydrolyzing inulin, by enzymatic methods, or by using micro-organisms.

The probiotic micro-organism may be selected from one or more micro-organisms suitable for animal consumption and which is able to improve the microbial balance in the intestine.

Examples of suitable probiotic micro-organisms include yeasts such as Saccharomyces, Debaromyces, Candida, Pichia and Torulopsis, moulds such as Aspergillus, Rhizopus, Mucor, and Penicillium and Torulopsis and bacteria such as the genera Bifidobacterium, Bacteroides, Clostridium, Fusobacterium,

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Melissococcus, Propionibacterium, Streptococcus, Enterococcus, Lactococcus, Staphylococcus, Peptostrepococcus, Bacillus, Pediococcus, Micrococcus, Leuconostoc, Weissella, Aerococcus, Oenococcus and Lactobacillus. Specific examples of suitable probiotic micro-organisms are: Saccharomyces cereviseae, Bacillus coagulans, Bacillus licheniformis, Bacillus subtilis, Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Enterococcus faecium, Enterococcus faecalis, Lactobacillus acidophilus, Lactobacillus alimentarius, Lactobacillus casei subsp. casei, Lactobacillus casei Shirota, Lactobacillus curvatus, Lactobacillus delbruckii subsp. lactis, Lactobacillus farciminus, Lactobacillus gasseri, Lactobacillus helveticus, Lactobacillus johnsonii, Lactobacillus reuteri, Lactobacillus rhamnosus (Lactobacillus GG), Lactobacillus sake, Lactococcus lactis, Micrococcus varians, Pediococcus acidilactici, Pediococcus pentosaceus, Pediococcus acidilactici, Pediococcus halophilus, Streptococcus faecalis, Streptococcus thermophilus, Staphylococcus carnosus, and Staphylococcus xylosus. The probiotic micro-organisms may be in powdered, dried form; especially in spore form for micro-organisms which form spores. Further, if desired, the probiotic micro-organism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix.

The nutritional agent may be administered to the pet as a supplement to the pet's normal diet or as a component of a nutritionally complete pet food. It is preferred to include the nutritional agent in a nutritionally complete pet food.

The nutritionally complete pet food may be in any suitable form; for example in dried form, semi-moist form and wet form. These pet foods may be produced as is conventional. Apart from the nutritional agent, these pet foods may include any one or more of a starch source, a protein source and lipid source. Suitable starch sources are, for example, grains and legumes such as corn, rice, wheat, barley, oats, soy, and mixtures of these. Suitable protein source; for example meat and meal, poultry meal, fish meal, soy protein concentrates, milk proteins, gluten, and the like. For elderly animals, it is preferred for the protein source to contain a high quality protein. Suitable lipid sources include meats, animal fats and vegetable fats. The choice of the starch, protein and lipid sources will be largely determined by the nutritional needs of the animal, palatability considerations, and the type of product produced. Further, various other ingredients, for example, sugar, salt, spices, seasonings, vitamins, minerals,

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flavoring agents, fats and the like may also be incorporated into the pet food as desired.

For elderly pets, the pet food preferably contains proportionally less fat than pet foods for younger pets. Further, the starch sources may include one or more of rice, barley, wheat and corn.

For dried pet foods a suitable process is extrusion cooking, although baking and other suitable processes may be used. When extrusion cooked, the dried pet food is usually provided in the form of a kibble. If a prebiotic is used, the prebiotic may be admixed with the other ingredients of the dried pet food prior to processing. A suitable process is described in European patent application No 0850569; the disclosure of which is incorporated by reference. If a probiotic micro-organism is used, the organism is best coated onto or filled into the dried pet food. A suitable process is described in European patent application No 0862863; the disclosure of which is incorporated by reference.

For wet foods, the processes described in US patents 4,781,939 and 5,132,137 may be used to produce simulated meat products. The disclosures of these patents are incorporated by reference. Other procedures for producing chunk type products may also be used; for example cooking in a steam oven. Alternatively, loaf type products may be produced by emulsifying a suitable meat material to produce a meat emulsion, adding a suitable gelling agent, and heating the meat emulsion prior to filling into cans or other containers.

The maximum level of prebiotic in the pet food is preferably about 20% by weight; especially about 10% by weight. For example, the prebiotic may comprise about 0.1% to about 5% by weight of the pet food. For pet foods which use chicory as the prebiotic, the chicory may be included to comprise about 0.5% to about 10% by weight of the feed mixture; more preferably about 1% to about 5% by weight.

If a probiotic micro-organism is used, the pet food preferably contains about 10⁴ to about 10¹⁰ cells of the probiotic micro-organism per gram of the pet food; more preferably about 10⁶ to about 10⁸ cells of the probiotic micro-organism per gram. The pet food may contain about 0.5% to about 20% by weight of the mixture of the probiotic micro-organism; preferably about 1% to about 6% by weight; for example about 3% to about 6% by weight.

The pet foods may contain other active agents such as long chain fatty acids. Suitable long chain fatty acids include alpha-linoleic acid, gamma linoleic acid, linoleic acid, eicosapentanoic acid, and docosahexanoic acid. Fish oils are a

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suitable source of eicosapentanoic acids and docosahexanoic acid. Borage oil, blackcurrent seed oil and evening primrose oil are suitable sources of gamma linoleic acid. Safflower oils, sunflower oils, corn oils and soy bean oils are suitable sources of linoleic acid.

If necessary, the pet foods are supplemented with minerals and vitamins so that they are nutritionally complete.

The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon the size or the pet, the type of pet, and age of the pet. However an amount of the pet food to provide a daily amount of about 1g to about 100g of prebiotic, or about 10⁶ to about 10¹² cells of the probiotic microorganism, would usually be adequate.

Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. Specific examples are now described for further illustration.

Example 1

Two dried pet foods are used in the study. Pet food A is a nutritionally complete dried pet food (ALPO Beefy Dinner). This is the control food. Pet food 1 is a nutritionally complete dried pet food which is substantially identical to Pet Food A but which contains 2% by weight of chicory. Both foods are nutritionally complete.

A group of 16 dogs are used in the study. Each group includes young and old dogs. The dogs are pre-fed for 8 weeks using Pet Food A. The dogs are then divided into 2 groups of 8 dogs and fed the following diets for 8 weeks:

| Group | Pet Food | | |
|-------|----------|--|--|
| A | A | | |
| 1 | 1 | | |

The dogs have free access to water and are fed once a day. An activity meter is attached to the collar of each dog and measurements are taken daily. The dogs are also visually evaluated for activity by kennel staff.

The condition of all dogs is visually and tactilely good as can be expected of normal, healthy dogs. However, the dogs which are fed Pet Food 1 are noticeably more active.

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Example 2

| | 5 . | The procedure of example 1 is repeated with 16 elderly dogs. The dogs have free access to water and are fed once a day. An activity meter is attached to the collar of each dog and measurements are taken daily. The body temperature, skin temperature at joints, and stifle diameter of each dog are also measured at regular intervals for signs of joint inflammation. The dogs are also visually |
|--|-----|--|
| | 10 | evaluated for activity by kennel staff. The condition of all dogs is visually and tactilely good as can be expected of normal, healthy dogs. However, the dogs which are fed Pet Food 1 are noticeably more active. Further, the dogs which are fed Pet Food 1 have less external signs of local joint inflammation. Further, the dogs appear to be in less pain. |
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- 1. A method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido-and lactic-bacteria in the gastro-intestinal tract of the pet.
- 2. A method according to claim 1 in which the nutritional agent is a component of a nutritionally complete pet food.
- 3. A method according to claim 1 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
 - 4. A method according to claim 3 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
 - 5. A method according to claim 1 in which the pet food further comprises a long chain fatty acid.
 - 6. A method according to claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat.
 - 7. A method for improving activity in an elderly pet, the method comprising administering to the pet a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
 - 8. A method according to claim 7 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
 - 9. A method according to claim 8 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 10. A method according to claim 7 in which the pet food contains about 0.1% to about 5% by weight of a prebiotic as the nutritional agent.

11. A method according to claim 7 in which the pet food contains about 10⁴ to about 10¹⁰ cells of a probiotic micro-organism per gram of the pet food as the nutritional agent. 5 12. A method according to claim 7 in which the pet food further comprises a long chain fatty acid. 13. A method according to claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat. 10 Į) 14. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a IJ F nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the dog. 15 æ 15. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the 20 gastro-intestinal tract of the dog. 16. A method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifidoand lactic-bacteria in the gastro-intestinal tract of the pet. 25 17. A method according to claim 16 in which the pet is an elderly dog. A method according to claim 16 in which the pet is an elderly cat. 19. A method for improving activity in an elderly dog, the method comprising 30 administering to the dog a nutritionally complete pet food which contains a

prebiotic selected from the group of inulin, fructooligosaccharides and plant

materials which contain inulin and/or fructooligosaccharides.

Abstract of the Disclosure

A method for improving activity in a pet; especially elderly cats and dogs.

The pets are administered to a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The nutritional agent may be a prebiotic or a probiotic micro-organism, or both.

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